violet radiation provided by the article, were adequate and effective in the treatment for (ultraviolet) various types of dermatitis, eczema, psoriasis, scalp diseases, rachitis, scrofulosis, glandular disturbances, and "epidimytis"; (red) in all cases where hyperthermia is indicated—in place of diathermy, acute and subacute inflamed processes, rheumatism, lumbago, sciatica, neuralgia, neuritis; affections of the middle ear, irritations of frontal and maxillary sinus, rhinitis, gallbladder infections, and gynecological disturbances; (blue) for the relief and abolishment of pains, for bactericidal effect in cases of: furunculosis, infected surface wounds, infections of the middle ear, sinus, and jaws; paradentitis, all types of burns, after X-ray treatments, necrosis, and frostbites; (neon) in all chronic conditions of rheumatic nature, rheumatism, sciatica, arthritis deformans, pyelitis, cystitis, gynecological disorders, "pleuritism," and phlebitis; and (green) various respiratory disorders, small and large bronchial infections, and virus flu's.

Model B–50 generator and *B–50 cabinet.* 502(a)—while held for sale, the accompanying labeling of the articles contained false and misleading representations that the articles were an adequate and effective treatment for rheumatoid arthritis, diseases of the heart, blood vessels, kidney, bladder, gallbladder, neuralgia, nervous disorders, respiratory infections, arteriosclerosis, grippe, eczema and dermatologic disorders, goiter, pneumonia, bronchial asthma, pleurisy, chronic constipation, phantom limb syndrome, high blood pressure, ankylosis, spondylitis, stomach disorders, menopausal difficulties, "Parkinson," diabetes, insomnia, obesity and other disease, and catarrhal disease; and that the articles would have a beneficial effect on the vegetative nervous system, increase circulation, intensify activity of the endocrine glands, accelerate metabolic processes, multiply white blood corpuscles, detoxicate the entire body, and kill disease germs; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use, and the articles were not entitled to any exemption from such requirement since the articles, because of their potentiality for harmful effect, method of use, and collateral measures necessary for their use, were not safe for use except under the supervision of a practitioner licensed by law to direct the use of such articles; and their labels failed to bear the statement "Caution: Federal law restricts this device to sale by or on the order of a _____," the blank to be filled with the designation of any practitioner licensed by the law of the State in which he practices, to use or order the use of the device.

DISPOSITION: 1–22–58. Consent—claimed by Karl Hausner, t/a Midwest Imports, and relabeled.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5489. Dextro-amphetamine sulfate timed disintegration capsules. (F.D.C. No. 40530. S. No. 69–500 M.)

QUANTITY: 28,500 capsules in bottles at Philadelphia, Pa.

SHIPPED: 1–28–57, from Brooklyn, N.Y., by Robin Pharmacal Corp.

LABEL IN PART: (Btl.) "500 T.D.C. (Timed Disintegration Capsule) Dextro-Amphetamine Sulfate 15 mgm. Each capsule contains 15 mgm. of Dextro-amphetamine sulfate in a special base that provides for timed disintegration

*See also Nos. 5481, 5483, 5484, 5486.

of the contents throughout a period of about 6–10 hours. This capsule is equivalent to one tablet of 5 mgm. potency taken three times a day. * * * Warning * * * Caution: Federal law prohibits * * * Supplied by Physicians Drug & Supply Co. Philadelphia, Pa."

LIBELED: 7–24–57, E. Dist. Pa.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it was represented to possess since the active ingredient was not gradually released over a 6–10 hour period but instead was released in a much shorter time; and 502(a)—the label statements which represented that the active ingredient was gradually released over a 6–10 hour period and that 1 capsule of the article was equivalent to 1 tablet of 5 mgm. potency taken three times a day were false and misleading as applied to the article, since the active ingredient was released in less than a 6-hour period and since 1 capsule of the article was not equivalent to 1 tablet of 5 mgm. potency taken three times a day.

DISPOSITION: 9–12–57. Default—destruction.

5490. Digitoxin tablets. (F.D.C. No. 40298. S. Nos. 68–386/88 M, 68–390 M, 68–392 M.)

QUANTITY: 15 ctns., 12 100-tablet btls. each; 1 drum of 66,400 tablets and 1 drum of 99,800 tablets; 13,500 tablets in 100-tablet btls.; and 1 ctn. containing 19 1,000-tablet btls., at New York, N.Y., in possession of Park Drug Co., Inc.

SHIPPED: The tablets were prepared from digitoxin powder shipped between Oct. 1954 and Nov. 1956, from Paris, France.

LABEL IN PART: (Btls. and drums) "Digitoxin Tablets * * * 0.1 mg. [or "0.2 mg."]."

RESULTS OF INVESTIGATION: Examination showed that the tablets contained not more than 82.6 percent of the declared amount of digitoxin.

LIBELED: 6–5–57, S. Dist. N.Y.

CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin, the minimum permitted by the standard.

DISPOSITION: 10–17–57. Default—destruction.

5491. Digitoxin tablets. (F.D.C. No. 40202. S. Nos. 62–918/9 M.)

QUANTITY: 58,400 tablets in 100-tablet btls. and 227,000 tablets in 1,000-tablet btls. at South Hackensack, N.J.

SHIPPED: Digitoxin powder was shipped on 5–7–56, from New York, N.Y.

LABEL IN PART: (Btls.) "Digitoxin U.S.P. 0.1 mg."

RESULTS OF INVESTIGATION: The tablets were prepared from the digitoxin powder shipped as described above.

Examination showed that the 58,400-tablet lot and the 227,000-tablet lot contained not more than 79.2 percent and 82.3 percent, respectively, of the declared amount of digitoxin.

LIBELED: 5–15–57, Dist. N.J.